

IN THE CLAIMS:

1. (Currently Amended) A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for one or more analytes comprising:

i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra characterized as having a negative slope for a continuous spectral segment from about 5 nm to about 200 nm in length said spectral segment including a principal calibration wavelength for said one or more analytes;

ii) calculating one or more ~~concentration~~ values from said measurement using said one or more calibration algorithms; and

iii) comparing said one or more ~~concentration~~ values with an assigned value given to said quality control material for each of said one or more analytes; and

~~iv) determining if there is a violation of a pre-established quality control rule,~~ thereby monitoring said one or more calibration algorithms of said apparatus.

2. (Original) The method of claim 1, wherein said one or more analytes is one or more analytes in a biological fluid selected from the group consisting of serum, plasma, urine, synovial fluid and cerebrospinal fluid.

3. (Original) The method of claim 2, wherein said one or more analytes is bilirubin, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

4. (Original) The method of claim 2, wherein said one or more analytes is an indicator of hemolysis, and in said step of measuring (step i)) said

spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

5. (Original) The method of claim 2, wherein said one or more analytes is a hemoglobin-based blood substitute, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

6. (Original) The method of claim 2, wherein said one or more analytes is met-hemoglobin, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

7. (Original) The method of claim 2, wherein said one or more analytes is methylene blue, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

8. (Original) The method of claim 2, wherein said one or more analytes is biliverdin, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

9. (Currently Amended) A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for a perfluorocarbon-like blood substitute, turbidity, or a combination thereof, wherein said turbidity is measured in concentration units of a lipid emulsion, comprising:

i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra within the range from about 700 nm to about 1100 nm;

ii) calculating one or more ~~concentration~~ values from said measurement using said one or more calibration algorithms; and

iii) comparing said one or more ~~concentration~~ values with an assigned value given to said quality control material for each of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof; ~~and~~

~~iv) determining if there is a violation of a pre-established quality control rule,~~ thereby monitoring said one or more calibration algorithms of said apparatus.

10. (Currently Amended) A method of monitoring calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for a perfluorocarbon-like blood substitute, turbidity, or a combination thereof wherein said turbidity is measured in concentration units of a lipid emulsion, comprising:

i) measuring absorbance of a quality control material with said apparatus to obtain a measurement, said quality control material exhibiting an absorbance spectra characterized as having a negative slope for a continuous spectral segment from about 5nm to about 400nm within the range of the absorbance spectra from about 700 nm to about 1100 nm;

ii) calculating one or more ~~concentration~~ values from said measurement using said one or more calibration algorithms; and

iii) comparing said one or more ~~concentration~~ values with an assigned value given to said quality control material for of said one or more of a perfluorocarbon-like blood substitute, turbidity, or a combination thereof, wherein said turbidity is measured in [concentration] units of a lipid emulsion; ~~and~~

~~iv) determining if there is a violation of a pre-established quality control rule,~~ thereby monitoring said one or more calibration algorithms of said apparatus.

11. (Original) The method of claim 1, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb,

carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

12. (Original) The method of claim 9, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

13. (Original) The method of claim 10, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

14. (Original) The method of claim 11, wherein said absorbance spectra of said one or more substances is altered by adding a spectral modifier.

15. (Original) The method or claim 14, wherein said modifier causes a non-additive spectral shift in said absorbance spectra.

16. (Original) The method of claim 15, wherein said modifier is selected from the group consisting of a polymer, a protein, amaranth, and a combination thereof.

17. (Original) The method of claim 16, wherein said polymer is selected from the group consisting of PVP and PEG.

18. (Currently Amended) A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

i) monitoring calibration of said apparatus as defined in claim 1;

~~ii) establishing that there is no violation of a pre-established quality control rule:~~

iii) ii) measuring absorbance values of said sample;

iv) iii) calculating an order derivative of absorbance of said sample;

and

~~v)~~ iv) calculating a concentration of said one or more analytes in said sample, by applying said at least one primary calibration algorithm to said order derivative of absorbance value.

19. (Currently Amended) A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

i) monitoring calibration of said apparatus as defined in claim 9;

~~ii) establishing that there is no violation of a pre-established quality control rule:~~

iii) ii) measuring absorbance values of said sample;

iv) iii) calculating an order derivative of absorbance of said sample;

and

~~v)~~ iv) calculating a concentration of one or more of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof, in terms of concentration of a lipid emulsion in said sample, by applying said primary calibration algorithm to said order derivative of absorbance value.

20. (Currently Amended) A reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

i) monitoring calibration of said apparatus as defined in claim 10;

~~ii) — establishing that there is no violation of a pre-established quality control rule:~~

iii) ii) measuring absorbance values of said sample;
iv) iii) calculating an order derivative of absorbance of said sample; and
v) iv) calculating a concentration of one or more of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof, in terms of concentration of a lipid emulsion in said sample, by applying said primary calibration algorithm to said order derivative of absorbance value.

21. (Original) The method of claim 18, wherein said one or more analytes is one or more analytes in a biological fluid selected from the group consisting of whole blood, serum, plasma, urine, synovial fluid and cerebrospinal fluid.

22. (Original) The method of claim 21, wherein said one or more analytes is bilirubin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

23. (Original) The method of claim 21, wherein said one or more analytes is an indicator of hemolysis, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

24. (Original) The method of claim 21, wherein said one or more analytes is a hemoglobin-based blood substitute, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

25. (Original) The method of claim 21, wherein said one or more analytes is met-hemoglobin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

26. (Original) The method of claim 21, wherein said one or more analytes is methylene blue, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

27. (Original) The method claim 21, wherein said one or more analytes is biliverdin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

28. (Original) The method of claim 18, wherein said quality control material comprises one or more substances selected from the group consisting of a dye, copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

29. (Original) The method of claim 28, wherein said absorbance spectra of said one or more substances is altered by adding a spectral modifier.

30. (Original) The method of claim 29, wherein said modifier causes a non-additive spectral shift in said absorbance spectra.

31. (Original) The method of claim 30, wherein said modifier is selected from the group consisting of a polymer, a protein, and amaranth.

32. (Original) The method of claim 31, wherein said polymer is selected from the group consisting of PVP and PEG.

33. (Original) A method for selecting one or more substances as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus comprising:

- i) identifying a principal calibration wavelength for each of one or more analytes;
- ii) screening absorption spectra of said one or more substances; and
- iii) selecting one or more of said substances exhibiting a negative slope of said absorbance spectra, for a continuous spectral segment from about 5 nm to about 200 nm in length, said spectral segment including said principal calibration wavelength.

34. (Original) The method of claim 33, wherein said one or more analytes is one or more analytes in a biological fluid selected from the group consisting of serum, plasma, urine, synovial fluid and cerebrospinal fluid.

35. (Original) The method of claim 34, wherein said one or more analytes is bilirubin, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

36. (Original) The method of claim 34, wherein said one or more analytes is an indicator of hemolysis, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

37. (Original) The method of claim 34, wherein said one or more analytes is a hemoglobin-based blood substitute, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

38. (Original) The method of claim 34, wherein said one or more analytes is met-hemoglobin, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

39. (Original) The method of claim 34, wherein said one or more analytes is methylene blue, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

40. (Original) The method of claim 34, wherein said one or more analytes is biliverdin, and in said step of selecting (step iii)), said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

41. (Original) The method of claim 33, wherein said quality control material comprises one or more substances, said one or more substances selected from the group consisting of a dye copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, and a perfluorocarbon-like blood substitute.

42. (Currently Amended) The method of claim 33 wherein in said step of identifying (step i)), said ~~principal~~ principal calibration wavelength of said analyte, and in said step of screening (step ii)) said absorption spectra of said one or more substances, are obtained on said spectrophotometric apparatus having one or more primary calibration algorithms.

43. (Currently Amended) A method for selecting one or more substances as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus for one or more of a

perfluorocarbon-like blood substitute and turbidity, wherein turbidity is measured in terms of concentration units of a lipid emulsion, comprising:

- i) identifying a principal calibration wavelength for each of one or more of said perfluorocarbon-like blood substitute and said turbidity;
- ii) screening absorption spectra of said one or more substances; and
- iii) selecting one or more of said substances exhibiting absorbance within the range from about 700 nm to about 1100 nm.

44. (Currently Amended) A method for selecting one or more substances as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus for one or more of a perfluorocarbon-like blood substitute and turbidity wherein turbidity is measured in terms of concentration units of a lipid emulsion, comprising:

- i) identifying a principal calibration wavelength for each of one or more of said perfluorocarbon-like blood substitute and said turbidity;
 - ii) screening absorption spectra of said one or more substances;
- and
- iii) selecting one or more of said substances exhibiting absorbance spectra as having a negative slope for a continuous spectral segment from about 5nm to about 400nm within the range of wavelengths from about 700 nm to about 1100 nm.

Claims 45-51 (Cancelled).

52. (Currently Amended) A quality control material for mimicking monitoring the calibration algorithms for two or more analytes comprising, one or more substances having a combined absorption spectrum exhibiting a negative slope for a one or more continuous spectral segment, wherein each of said one or more continuous spectral segment is from about 5 nm to 200 nm in length, in a portion of an absorption spectrum, including and wherein said one or more

continuous spectral segment includes one or more principal calibration wavelengths, for said two or more analytes.

53. (Original) The quality control material of claim 52, wherein one of said two or more analytes is bilirubin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 450 nm to about 600 nm.

54. (Original) The quality control material of claim 52, wherein one of said two or more analytes is an indicator of hemolysis, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total Hb, Oxy-Hb, and "total Hb minus met-Hb".

55. (Original) The quality control material of claim 52, wherein said two or more analytes are selected from the group consisting of whole blood, serum, plasma, synovial fluid, cerebrospinal fluid, urine, mucus, lymphatic fluid, semen and feces.

56. (Original) The quality control material of claim 52, wherein one of said two or more analytes is a hemoglobin-based blood substitute, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 700 nm.

57. (Original) The quality control material claim 52, wherein one of said two or more analytes is met-hemoglobin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 610 nm to about 690 nm.

58. (Original) The quality control material claim 52, wherein one of said two or more analytes is methylene blue, and said spectral segment is selected

from wavelengths of said absorbance spectra of from about 650 nm to about 750 nm.

59. (Original) The quality control material claim 52, wherein one of said two or more analytes is biliverdin, and said spectral segment is selected from wavelengths of said absorbance spectra of from about 650 nm to about 800 nm.

60. (Original) The quality control material claim 52, wherein one of said two or more analytes is either a simulator of turbidity or a perfluorocarbon-like blood substitute, said quality control material further characterized as having an absorbance spectrum within the range of from about 700 nm to about 1100 nm.

61. (Original) The quality control material claim 52, wherein one of said two or more analytes is either a simulator of turbidity or a perfluorocarbon-like blood substitute, said absorption spectrum of said quality control material further characterized as having a negative slope for a continuous spectral segment from about 5nm to about 400nm within the range of from about 700 nm to about 1100 nm.

62. (Original) The quality control material of claim 52, further comprising one or more substances selected from the group consisting of a dye copper sulfate, total Hb, Oxy-Hb, carboxy-Hb, "total Hb minus met-Hb", cyanmet-Hb, a Hb-based blood substitute, a lipid emulsion, a perfluorocarbon-like blood substitute, and a combination thereof.

63. (Currently Amended) The quality control material of claim 64 60, wherein an absorbance spectrum of said one or more substances is altered by adding a spectral modifier.

64. (Original) The quality control material of claim 63, wherein said modifier causes a non-additive spectral shift in said absorbance spectra.

65. (Original) The quality control material of claim 64, wherein said modifier is selected from the group consisting of a polymer, a protein, and amaranth.

66. (Original) The quality control material of claim 65, wherein said polymer is selected from the group consisting of PVP and PEG.

Claims 67-96 (Cancelled).

97. (Original) The quality control material of claim 62, wherein said one or more substances is not supplemented with bilirubin.